§ 111.375 Under this subpart K, what records must you make and keep?

(a) You must make and keep records required under this subpart K in accordance with subpart P of this part.

(b) You must make and keep records of the written procedures for manufacturing operations.

Subpart L—Production and Process Control System: Requirements for Packaging and Labeling Operations

§ 111.403 What are the requirements under this subpart L for written procedures?

You must establish and follow written procedures for packaging and labeling operations.

§ 111.410 What requirements apply to packaging and labels?

(a) You must take necessary actions to determine whether packaging for dietary supplements meets specifications so that the condition of the packaging will ensure the quality of your dietary supplements;

(b) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies. Label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations; and

(c) You must examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record; and

(d) You must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution.

§ 111.415 What requirements apply to filling, assembling, packaging, labeling, and related operations?

You must fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. You must do this using any effective means, including the following:

(a) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary supplement packaging, as appropriate;

(b) Protecting manufactured dietary supplements from contamination, particularly airborne contamination;

(c) Using sanitary handling procedures;

(d) Establishing physical or spatial separation of packaging and label operations from operations on other components and dietary supplements to prevent mixups;

(e) Identifying, by any effective means, filled dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;

(f) Assigning a batch, lot, or control number to:

(1) Each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement; and,

(2) Each lot of dietary supplement, from a finished batch of dietary supplement, that you distribute to another person for packaging or labeling.

(g) Examining a representative sample of each batch of the packaged and labeled dietary supplement to determine whether the dietary supplement meets specifications established in accordance with § 111.70(g); and

(h) Suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

§ 111.420 What requirements apply to repackaging and relabeling?

(a) You may repackage or relabel dietary supplements only after quality control personnel have approved such repackaging or relabeling.

(b) You must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with § 111.70(g).